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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,049	06/22/2001	Yasuki Kato	506.40278X00	1134

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,049

Applicant(s)

KATO ET AL.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' amendment and response filed 01/02/2004 in response to Office Action mailed 07/01/2003 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-5, 7-9, 11-13, 15-23, 25-27 and 29-30 have been amended.
3. Claims 31- 60 have been added.
4. Claims 1-60 are pending and are examined on merits.

Claim Rejections - 35 U.S.C. § 112

5. Claims 1-30 and newly added Claims 31-60 stand rejected under 35 U.S.C. § 112, first paragraph for the reasons of record on page 3, items 9 and 10 of the Office Action cited *supra*.

In response to the rejections under 35 U.S.C. § 112, first paragraph in the Office Action cited *supra*, applicants argue that claims have been amended "so that the compound having the free amino group is defined according to what the examiner has indicated to be enabled" and "the sugar having the reducing power is defined according to the sugars named in the specification on page 5, Lines 10-30".

Applicants' arguments regarding the rejections under 35 U.S.C. § 112, first paragraph in the Office Action mailed 07/01/2003 cited *supra* have been fully considered but are not deemed persuasive for the reasons of record on page 3, items 9 and 10 of the Office Action cited *supra* and further because applicants' amended claims still cite compounds having free amino acids and a long list of sugar having reducing power. As already stated at items 9 and 10 of the Office Action mailed 07/01/2003, according to the examples presented in the currently as written specification, applicants' claimed invention is only enabled for bovine pancreatic insulin, Enkephalin, doxorubicin hydrochloride and other peptides but not for all the compounds having a free amino group. Similarly, applicants' claimed invention is only enabled for beta- lactose and sialyllactose as the sugars having the reducing power and despite a long contemplated list of sugars having reducing power, Applicants' preferred sugars with reducing power are: disialyllactose, galactose, lactose and sialyllactose.

6. Claims 1-30 and newly presented Claims 31-60 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 1 and 31 are rendered vague and indefinite by the use of parentheses. The use of parentheses encompassing terminology in the claims is indefinite because it is unclear if what is stated within the parentheses is a further limitation or simply alternative meaning.
- The recitation, "derivative" in claim 3 renders that claim unclear and confusing, and therefore indefinite because the term does not clearly define as to how similar a compound should be of the base compound to be called derivative, i.e. the term does not define the metes and bounds of the claimed subject matter.
- The phrase "modified with or encapsulated in" renders Claims 5, 9, 13, 17, 23, 35, 39, 43, 47, 53 and 57 confusing. Applicants should clarify whether this term is open, like the conventional term "comprising", or what does this term define? The Examiner suggests that the applicants should replace this phrase with the transitional phrase "further comprising". Applicants should also clearly state whether the pharmaceutical preparation further comprises said compounded or said compound is encapsulated in a pharmaceutical carrier.
- The phrase, "or included encapsulated" renders Claim 5 indefinite because it is unclear as to what is being claimed in said claim.
- The phrase, "which can be obtained" in Claims 5, 9, 13, 17, 23, 35, 39, 43, 47, 53 and 57 renders those Claims indefinite because it is unclear as to how the disclosed/claimed compound will be prepared by "reacting a compound having free amino group with a sugar having the reducing power". Applicants should delineate each and every step in the claim language because a method is being disclosed/claimed. Furthermore, the phrase, "can be obtained" gives the connotation of a future occurrence without affirmative claiming the disclosed/claimed process.
- Claims 5, 9, 13, 35, 39, 43, 47, 53 and 57 are rendered vague and unclear because it is not clear what is being encapsulated in a pharmaceutical carrier, the resultant compound from the reaction of "a compound having a free amino group" with "a sugar having reducing power" or the "compound having free amino group" or the "sugar having reducing power"?
- Claim 8 is rendered indefinite because of the term "included". This term is similar to term "include" and is therefore, indefinite because it is not clear whether the term is open, like the conventional term "comprising" or whether the term excludes other ingredients, like the term "consisting of". Examiner suggests that the applicants use the transitional phrase "comprises".

Since all other claims depend directly or indirectly from the rejected claim (i.e., Claim 1 or 31) Claims 2-30 and 32-60, also stand rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

7. Claims 1-30 and newly added claims 31-60 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for the reasons of record on page 4, item 12, first and second bullets and third bullet on Page 5 of the Office Action cited *supra*.

In response to this rejection applicants argue that:

- Claim 1 has been rewritten for greater clarity by labeling each of the compounds,
- In response to the rejection to phrase "which can be obtained" in Claims 1, 5, 9, 13, 17, 23 and 27, applicants argue that So long as two components, one having a free amino group and other a sugar having reducing power are reacted to prepare the claimed pharmaceutical compound, any step may be applied and it is not necessary to delineate each and every step,
- The phrase "modified with or included in" render claims 5, 9, 13, 17 and 23 indefinite, applicants argue that these claims have been amended as four different embodiments, however embodiments 3-4 still recite the phrase "can be obtained".

Applicants' arguments regarding the rejection to claims 1-30 under 35 U.S.C. § 112, second paragraph in the Office mailed 07/01/2003 have been fully considered but are not persuasive for the reasons of record cited *supra* and additional reasons given below:

- Claim 1 is still rendered unclear and indefinite. The labeling of compounds as I II and III does not clarify as to what is being released, the compound with free amino group, the sugar having the reducing power, or the product of the reaction between the compound with free amino group and the sugar having the reducing power?

Since all other claims depend directly or indirectly from the rejected claim (i.e., Claim 1 or 31) Claims 2-30 and 32-60, also stand rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections – 35 U.S.C. § 102

8. Claim 1 and newly added Claim 31 stand rejected under 35 U.S.C. §102(b) as anticipated by Sessler et al. (U.S. Patent 5,580,543) for the reasons of record at page 6, item 15 of the Office Action mailed 07/01/2003.

In response to this rejection applicants argue that "Claims 1-4 was rejected" and argue that Sessler et al. do not disclose a saccharide outside the texaphyrin moiety and further that the mechanism taught in Sessler et al. is different than that Claimed in the instantly claimed invention. Applicants further argue, "preparation of the present invention comprises a compound that can be obtained".

Applicants' arguments regarding the rejection to claim 1 under 35 U.S.C. § 102(b) in the Office mailed 07/01/2003 have been fully considered but are not persuasive for the reasons of record cited *supra* and for additional reasons given below:

Contrary to applicants' argument, Examiner has rejected only Claim 1 in the Office Action mailed 07/01/2003. Applicant's arguments regarding the prior art reference have been fully considered but are not persuasive. The claims remain anticipated and obvious to an artisan of ordinary skill because Sessler et al. clearly teach that their invention is not limited to said structure (Column 7, Lines 31-34) and further teach that saccharides with reducing power are: D-galactose, D-glucose, lactose, D-mannose and others (Column 8, Lines 26). Furthermore, the mechanism of action of a composition does not materially change a composition and is accordingly, not given any patentable weight.

Claim Rejections - 35 U.S.C. § 103

9. Claims 1-30 and newly added Claims 31-60 stand rejected under 35 U.S.C. § 103 (a) as obvious over Sessler et al. (U.S. Patent 5,580,543) in view of Katsukiyo (JP-07-061999) and Masashi et al (JP 9-263579).

In response to this rejection applicants argue that the instantly claimed invention is unobvious over because Sessler et al., "do not disclose or suggest that a sugar having the reducing power binds to a compound having a free amino group". Applicants asserting that "Katsukiyo discloses a sugar modified protein, wherein lactose lactone is reacted with a protein, and Masashi discloses a pharmaceutical preparation made from enclosing a drug made from protein inserted into a liposome etc.", "the above two references do not disclose nor suggest a combination of a compound having a free amino group and a sugar having a reducing group". Applicants further argue that their instantly claimed invention is unique because the pharmaceutical preparation claimed instantly comprises a compound prepared by reacting a sugar having reducing power with a compound having a free amino group, wherein the pharmaceutical preparation in response to changes in pH releases the said compound having a free amino group.

Applicants' arguments regarding the rejection to claims 1-30 under 35 U.S.C. § 103(a) in the Office mailed 07/01/2003 have been fully considered but are not persuasive for the reasons of record cited *supra*.

10. In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, those reasons are cited at pages 7-9 of the Office Action mailed July 01, 2003. Furthermore, a rejection under 35 U.S.C. § 103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

CONCLUSION

11. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No Claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571)-272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (571)-272-0926 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(571)-272-0923

March 29, 2004



CHRISTOPHER R. TATE
PRIMARY EXAMINER